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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,199	06/23/2001	David O'Leary	TEVNHC 3.0-031	8435
530 7590 09/04/2008 LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090				
EXAMINER				
PATEL, NIHIR B				
ART UNIT		PAPER NUMBER		
3772				
MAIL DATE		DELIVERY MODE		
09/04/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/888,199

Applicant(s)

O'LEARY, DAVID

Examiner

NIHIR PATEL

Art Unit

3772

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06.02.2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 16 is/are rejected.
- 7) ☒ Claim(s) 3-15 and 17 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/88)
- Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed on June 2nd, 2008 have been fully considered but they are not persuasive. The applicant argues that Ambrosio does not teach a cup assembly movably received in the channel. The examiner disagrees with the applicant's argument. Ambrosio does teach a cup assembly movably received in the channel (col. 15 lines 15-25 clearly states that "During initial priming rotation, metered dose hole passes under manifold 46 and substantially holes 96 and 98") implies that the cup assembly is movably received in the channel. The applicant further argues that Ambrosio does not disclose a second sealing surface adapted to seal the pressure relief port when the recess is aligned with the dispensing port and to unseal the pressure relief port when the recess is not aligned with the dispensing port. The examiner disagrees with the applicant's argument. Ambrosio does teach a second sealing surface adapted to seal the pressure relief port when the recess is aligned with the dispensing port and to unseal the pressure relief port when the recess is not aligned with the dispensing port (col. 15 lines 15-25 clearly states that "During initial priming rotation, metered dose hole passes under manifold 46 and substantially holes 96 and 98") implies that the second sealing surface is adapted to seal the pressure relief port when the recess is aligned with the dispensing port and to unseal the pressure relief port when the recess is not aligned with the dispensing port. The applicant states and argues that "since powder retainer 186 travels with metering dose plate 180, the metering dose plate simply cannot have both sealed and unsealed positions relative to the powder retainer. The applicant makes specific references to col. 14 lines 3-10 and 24-30). After reading col. 4 lines 3-10 and 24-30 of the Ambrosio's reference, the examiner disagrees with the applicant's argument. The cited

references does not state that the powder retainer travels with metering dose plate.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims **1, 2 and 16** are rejected under 35 U.S.C. 102(e) as being anticipated by Ambrosio et al. (US 6,240,918).

4. **As to claim 1**, Ambrosio teaches an apparatus that comprises a sealed reservoir **22** (see **figure 3; column 9 lines 50-60**) including a dispensing port (see **figure 5; column 10 lines 35-50**); a linear channel communicating with the dispensing port and including a pressure relief port **186** (see **column 19 lines 25-35; the powder retainer acts like a pressure relief port since it is made out of woven mesh**); a conduit **64** providing fluid communication between an interior of the sealed reservoir and the pressure relief port **186** of the channel; a cup assembly **180** movably received in the channel and including a recess **184** adapted to receive medicament from the reservoir when aligned with the dispensing port (see **column 15 lines 10-20**), a first sealing surface adapted to seal the dispensing port when the recess is not aligned with the dispensing port (see **column 26 lines 55-65**) and a second sealing surface adapted to seal the pressure relief port when the recess is aligned with the dispensing port and to unseal the pressure relief port

when the recess is not aligned with the dispensing port (**see column 26 lines 63-67 and column 27 lines 1-15**).

5. **As to claim 2**, Ambrosio teaches an apparatus wherein the cup assembly includes a sealing spring **290** biasing the first sealing surface against the reservoir (**see figure 3**).
6. **As to claim 16**, Ambrosio teaches an apparatus wherein the reservoir includes a volume of dry powdered medicament (**see column 9 lines 40-50**).

Allowable Subject Matter

7. Claims **3-15 and 17** are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art does not teach a reservoir that includes a collapsible bellows adapted to increase pressure within the interior of the reservoir upon being collapsed, when the pressure relief port is sealed. The prior art also does not teach a cup assembly that includes a cup received in a cup sled movable within the channel, the cup defining the recess and the first sealing surface, and the sled defining the second sealing surface.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NIHIR PATEL whose telephone number is (571)272-4803. The examiner can normally be reached on 7:30 to 4:30 every other Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nihir Patel/
Examiner, Art Unit 3772
/Patricia Bianco/
Supervisory Patent Examiner, Art Unit 3772

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